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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,298	04/20/2007	Fiona Becker	10582.204-US	1084
25908 7590 09/15/2011 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110				
EXAMINER BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1781				
NOTIFICATION DATE		DELIVERY MODE		
09/15/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary

Application No.

10/588,298

Applicant(s)

BECKER ET AL.

Examiner

HAMID R. BADR

Art Unit

1781

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-10 and 14-20 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-10 and 14-20 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-884)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Applicants' amendment filed 8/01/2011 is acknowledged.

Claims 1-10 and 14-20 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 is indefinite for "and heating the dough". It is not clear whether actual baking at high temperature is meant by this phrase or simply heating at any arbitrary temperature is meant.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (US 6,254,903; hereinafter R1) in view of Viet et al. (1991, Purification and properties of β -1,4-xylanase from *Aeromonas caviae* W-61; hereinafter R2)

6. R1 discloses a method of producing baked goods using enzymes leading to prevention of staling. (abstract)

7. R1 discloses that their inventive amylase is a maltogenic amylase producing 50-60 wt. % of maltose from wheat starch (col. 4, lines 20-25). R1 discloses the application of maltogenic amylase in baking. R1 discloses that the enzyme can be mixed with the very flour used for making the baked article. The enzyme can also be contained in the baking ingredients added to the flour or dough or mixed directly with the dough. (col. 4, line 66 to col. 5; line2)

8. R1 teaches of adding the freshness-retaining enzyme in a quantity which is effective for prevention of staling. (col. 5, lines 4-6) Given that staling is prevented, it is clear that shelf life is increased.

9. R1 teaches that the freshness-retaining enzyme can be added on its own as the only enzymatic active substance. It is also possible to add other enzymes including xylanases. R1 further discloses that the addition of xylanase with baking activity appears to be particularly effective in this connection. It increases the volume of the baked article particularly effectively and leads to remarkably soft crumb. R1 explains that part of the insoluble pentosans is made soluble or water-swellable and these compounds in turn will increase the water absorption (i.e. retention). R1 discloses that xylanases are advantageously added with the maltogenic amylase. (col. 5, lines 45-65)

10. Since R1 clearly discloses that the combination of xylanase and maltogenic amylase brings about increased crumb softness, increased water absorption (retention) and prevention of staling (i.e. increased product shelf life), the amendment to claim 1

reciting "xylanase is added in an amount effective for increasing the shelf life of the dough based product" would have been obvious to an ordinary skill in the art.

11. However, R1 is silent regarding the use of the specific *Paenibacillus pabuli* xylanase in baking.

12. R2 discloses the purification and properties of β -1,4-xylanase from *Aeromonas caviae* W-61 (presently known as *Paenibacillus* sp. W-61). This enzyme has 96.7% similarity with the presently claimed xylanase. (Data base: Uniprot. ID Q1XGE6-9BACL)

13. Therefore, the presently claimed xylanase of *Paenibacillus* sp. was known in the art at the time the invention was made. Since R1 discloses the incorporation of xylanase enzymes to prevent staling and to increase the shelf life of baked products, the inclusion of xylanase in the dough would have been motivated and the added xylanase, including the known *Paenibacillus* xylanase, would have been expected to demonstrate the same or similarly-effective properties regarding the prevention of staling and increased shelf life of baked products and thus obvious to an artisan.

14. Since the claimed xylanase was known in the art, its purification, cloning, expression, and production, using the known techniques in the art, would have been motivated and obvious. The enzyme, as shown by R2, functions as an endo-xylanase capable of hydrolyzing β -1,4 glycosidic bonds in xylans. Therefore, it is expected that the recombinant xylanase functions as the native enzyme regarding the hydrolysis of xylans.

15. It is noted that a specific strain (DSM 16232) is being claimed as the source of the xylanase enzyme. However, since *Paenibacillus* sp. was known to possess

xylanolytic enzyme, the screening of strains having xylanase activity, following standard methods known in the art, would have been motivated. Once the candidate is screened out, the enzyme would have been purified and cloned following the known techniques in the art. The ultimate incorporation of either the native or the recombinant enzyme into dough to improve the shelf life of the baked product was motivated by R1 therefore, its utilization in baking would have been obvious and within the skill of the art.

16. Then, it would have been obvious to those of ordinary skill in the art, at the time the invention was made, to prepare xylanase(s) from *Paenibacillus pabuli*, including the presently claimed strain, produce recombinant xylanase utilizing the known cloning protocols, ultimately recover the enzymes from the cell free extract of the host cells and apply the enzyme (In pure or partially purified forms) in baking as disclosed by R1. One would do so to take advantage of the xylanase enzyme of a specific source in baking and expect to observe the improvement in shelf life of baked products as disclosed by R1. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success to screen for xylanase producing *Paenibacilli*, and clone the enzyme in suitable host cells for over-expression of the enzyme and ultimately apply the enzyme in baking.

Response to Arguments

Applicants' arguments have been considered. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that the phrase "and heating the dough" in claim 1 is definite because it is understood that heating is referring to baking the dough.

a. The examiner does not agree. The word 'baking' is a well understood word in the art implying that the dough is cooked at high temperature to produce the baked product. The phrase "heating the dough" may simply mean elevating the temperature of the dough so that the added enzymes do their jobs at a higher reaction rate. Therefore, it may mean processing the dough at a higher temperature than the regular ambient for specific purposes.

2. Applicants argue that Example 3 shows that the xylanase of the invention increases the amount of free water which has been described in the literature to correlate to moistness of bread crumb more than prior art xylanase.

a. Xylanases used in baking are all endo-1,4-xylanases and are used for the hydrolysis of hemicellulase. Therefore, their effects regarding the free water are expected to be similar. R1 clearly uses the xylanase with maltogenic amylase to increase the shelf life of the baked bread. The improvement in shelf life is brought about by an increase in free water.

3. Applicants argue that the combination of xylanase and maltogenic amylase produced a baked product which was perceived as more moist than bread made with the prior art xylanase and amylase.

a. This argument is not persuasive because the xylanase and amylase of prior art in Example 3, are not the xylanase and amylase of R1. Therefore, this comparison is not an objective comparison. On the other hand the unit of the instantly

claimed xylanase in Example 3, is mg/kg. However, the prior art is being reported as units of enzyme activity. Therefore, the specific activities of the xylanases on the same substrate and under the same assay conditions are not being compared. Lastly, the data as depicted in Example 3, are single data points. It is unclear whether these data are significantly different when comparing the characteristics of the baked products.

A prima facie case of obviousness is established where the Examiner demonstrates that the invention is nothing more than the predictable result of a combination of familiar elements according to known methods. *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); *Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325, 1338, (Fed. Cir. 2010) ("If a person of ordinary skill, before the time of invention and without knowledge of that invention, would have found the invention merely an easily predictable and achievable variation or combination of the prior art, then the invention likely would have been obvious.").

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1781

HAMID R BADR
Examiner
Art Unit 1781